A 3 Outcome Assessment Methodology in Peripheral Arterial Disease

A 3.1 Impetus for Outcomes Research

Although the value of lifesaving therapies is boldly displayed in both the medical and lay press, most medical treatment provided in the developed countries is directed toward improvement in quality of life. Interventions for claudication and CLI are examples of therapies directed toward the relief of symptoms and improvement in quality of life. The goal of all such interventions is to reduce the adverse impact of an illness or disorder on the patient's life and improve the patient's sense of well-being and productivity. As the costs of health care continue to spiral upward, governments and third-party payers are seeking to contain costs by limiting reimbursement to those therapies proven to be effective, either in saving lives or improving quality of life. Ultimately, the decision to advocate a treatment, and the decision by payers and regulatory bodies for reimbursement involves a trade-off between the additional costs incurred and effectiveness gained by performing that treatment.[1]

Multiple studies have been published reporting the experience of centers on the short and long-term results of performing interventions for PAD. Unfortunately, these studies are frequently difficult to compare and to apply directly to patient management. This is attributable to the differences in study populations with respect to disease severity and risk factors, differences in reporting methods such as including versus excluding technical failures in the patency results, and the lack of outcome data relevant to the patient such as walking ability and quality of life.[2,3,4,5,6] In terms of the levels of evidence according to the Sackett classification, these studies all fall in the lowest level category V.

To permit delineation of appropriate reporting criteria, the Ad Hoc Committee on Reporting Standards of the Vascular Societies established categories of vascular disease commonly seen in clinical practice.[2,5] These criteria have served to improve the published data available to the vascular specialist for the diagnosis and treatment of vascular disease and have led the way to a standardized methodology for reporting the results of treatment. Such standardization of methodology is important not only for current therapies but also for the assessment of new technologies and techniques in this time of rapid technological proliferation. This fact has been recognized by governmental regulatory agencies and payers.

To evaluate therapeutic effectiveness requires the use of outcomes measures that assess factors that affect patients directly (eg, physical and social functioning and pain) rather than only clinical measures (eg, laboratory test scores).[8] ABPIs, for example, are typically of interest to the physician because they are measurable semi-objective outcomes of the intervention performed. Ultimately, patients are not interested in their ankle pressures or patency of their arteries but rather how far they can walk, limb salvage, and surviving any procedure performed—measures of overall effectiveness (Table 7). The assessment of a therapeutic endeavor by outcome measures and clinical parameters can yield different results.

Table 7. Examples of outcome measures of effectiveness

Technical success of revascularization procedure
Death as a result of revascularization procedure
Short- and long-term morbidity as a result of revascularization procedure
Change in mean ankle-brachial indices
Survival/life expectancy
Amputation-free survival/life expectancy
Quality-adjusted survival/life expectancy
Generic health status (eg, medical outcomes study short form questionnaire with 36 items [SF-36])
Disease-specific measures of functional status (eg, walking impairment questionnaire [WIQ], walking distance)
Valuational measures/utility assessment (eg, visual rating scale [VRS], Health Utilities Index [HUI], European quality of life instrument [EuroQol])

A 3.2 Outcome Measures of Effectiveness

The outcome after treatment of PAD should focus on the degree of change in clinical and functional status in relation to the pretreatment status.[5] After surgical and percutaneous procedures, a number of intermediate outcomes potentially related to the procedure are important in assessing the overall outcome after treatment. These are, for example, technical success of the procedure and procedural complications, resulting in either short- or long-term morbidity. Furthermore, for decision-making purposes it is necessary to distinguish the long-term and short-term effects of complications on life expectancy, quality of life, or costs. Systemic complications (eg, MI, stroke) generally have important short- and long-term effects, whereas local complications (eg, hematoma, pseudoaneurysm, wound infection) generally only have short-term effects.

A 3.2.1 Technical Success

Technical success is particularly relevant to percutaneous interventions. Without technical success, one cannot expect a clinically successful outcome, and technical success is not always achieved. Furthermore, immediately after percutaneous angioplasty, some measurement is required to determine whether further intervention is necessary during the same procedure in the form of angioplasty with a larger balloon or stent placement. Angiographic definitions of technical success after angioplasty have a poor reproducibility. A high interobserver variability has been demonstrated between radiologists performing the procedure and an independent reader.[9] Furthermore, the angiographic residual stenosis correlates poorly with the postprocedural intraarterial pressure gradient.[9] Measuring pressure gradients across a treated segment, with pharmacological vasodilatation, is currently the most widely used measure of technical success after percutaneous angioplasty. Intravascular ultrasound is potentially the most accurate method of detecting a technical successful result in large vessels. Technical failures should be included in the assessment of overall outcome.

A 3.2.2 Procedural Complications

One of the main problems with determining and reporting complications is that it can be difficult to distinguish procedural from nonprocedural mortality and morbidity. The distinction can be very subjective. Thus, by convention, 30-day mortality and morbidity rates should be reported. It would be useful to define complications as any untoward event following the procedure with either a lasting negative effect (eg, MI, death) or requiring a change in management (eg, extra day in hospital of observation, blood transfusion). Using this definition, for example, minor hematomas after angioplasty that have no consequence are not counted as a complication. A hematoma is only counted as a complication if the patient is observed longer, recuperates longer, requires a blood transfusion, or requires evacuation of the hematoma. There are multiple proposed definitions of minor and major complications.

A 3.2.3 Criteria for Success

The short- and long-term success rates after an intervention depend on the definition used for success.[5] For example, van Andel et al[10] reported far higher than average results after iliac PTA because they used the presence of a palpable common femoral artery (CFA) pulse as a measure of success. Conversely, Johnston et al,[11] by using the criteria of clinical improvement plus an increased ABPI, reported lower than average results because subsequent occlusive events distal to the percutaneous transluminal angioplasty (PTA) (typically superficial femoral artery [SFA] occlusion) were wrongly included as PTA failure. Table 8 illustrates how patency results may vary by applying different criteria of a successful outcome to the same data.

ABPI is commonly used as an objective measure of success but may be influenced by disease, or treatment, at other sites. Furthermore, exercise or drug regimens that improve walking distance do not necessarily improve ABPI or blood flow.[13] The results of infrapopliteal PTA are very difficult to ascertain because this is usually accompanied by treatment at other sites. Furthermore,

Table 8: Different patency rates obtained by applying criteria of a successful outcome to exactly the same data[12]

Criteria used to measure successful outcome	*Patency rate (%)*
Δ Thigh:brachial index >0.1	89
Δ Thigh:brachial index >0.1 plus no clinical deterioration	79
Δ Ankle:brachial index >0.1	68
Δ Ankle:brachial index >0.1 plus no clinical deterioration	58
Δ Ankle:brachial index plus clinical improvement	54

some early reports of surgical series, when compared with audited data, were unduly optimistic.[14,15] Similarly, it is well known that results of personal or institutional series are often significantly better than those from strictly controlled and audited multicenter trials.

Clinical success in the surgical and radiological literature is defined as some combination of symptomatic improvement and objective hemodynamic success. After the first publication of the reporting standards for surgical and percutaneous interventions, many authors combined symptomatic criteria and objective hemodynamic criteria with an 'or.' This would have been classified as at least +1 level of improvement[2] and implies using a very lenient criteria for success. The revised reporting standards recommend a more stringent success criteria (at least +2 level of improvement), stating that both symptomatic improvement 'and' objective hemodynamic improvement are required for success.[5] A distinction is made between i) clinical success as determined by symptomatic improvement 'and' objective hemodynamic improvement of the entire limb, ii) hemodynamic success, which applies to objective improvement of the entire limb, and iii) patency, which applies to the revascularized or bypassed segment only.[5] Furthermore, it is important to distinguish primary, assisted primary, and secondary patency.

Primary patency implies uninterrupted patency following only the procedure being evaluated. *Assisted primary patency* is used in reporting surgical interventions and implies that cases undergoing a revision of the graft before graft occlusion, that is, prophylactic interventions, are not counted as failures if the revision salvages the graft. *Secondary patency* implies patency following the initial procedure or following a reintervention to restore patency of an occluded graft or vessel. After either a surgical or endovascular procedure, secondary patency implies the need in some patients for reopening of the treated segment by a second intervention. (See also A 3.2.9, Patency, p S42.)

Apart from measuring symptomatic improvement, objective improvement, and patency, outcomes directly relevant to the patient should be measured. Numerous instruments have been developed to measure health-related quality of life that are useful in this regard. A distinction should be made between the descriptive and valuational instruments. Whereas *descriptive instruments* provide scores for quality of life on various dimensions, *valuational measures* provide a quantitative assessment of quality of life. *Descriptive instruments* include generic and disease-specific health status questionnaires. These yield scores describing the respondent's mobility, functioning, mental health, and overall well-being. *Valuational instruments* yield holistic numerical values of the quality of life on a scale from 0.0 (usually anchored as death) to 1.0 (usually anchored as perfect health). Such values are required in cost-effectiveness analysis by health care purchasers when deciding whether a particular gain in effectiveness justifies the additional cost, for example, use of stent placement rather than, for example, balloon angioplasty alone (see also A 4, Economic Aspects of PAD, p S45).

Studies evaluating the relationship between various outcome measures have shown moderate to poor correlation. For example, the ABPI does not correlate well with the degree of exercise impairment, and changes in ABPI do not correlate well with changes in walking distance.[16] The correlation between various health status questionnaires and walking distance or ABPI has been

demonstrated to be poor to moderate.[17,18,19] The relationship between ABPI or angiographic findings and quality-of-life measures also appears to be weak.[20] Similarly, the relationship between descriptive quality-of-life measures and valuational measures in patients with PAD appears weak.[21] These results seem to imply that "success" of an intervention is a multidimensional entity requiring consideration of traditionally used measures of medical effectiveness (eg, ABPI, patency), walking ability of the patient (functional status either measured directly or with the walking impairment questionnaire), descriptive health status measures (eg, SF-36), and measures valuing quality of life (eg, HUI, EuroQol).

Recommendation 1: Outcome measures in peripheral arterial disease
In determining the baseline severity of disease and changes in response to treatment, the following outcomes should be documented:

- Objective/hemodynamic status of the limb
- After revascularization: patency of the revascularized segment
- Symptomatic status of the limb
- General quality of life of the patient
- Value or utility assessment of quality of life of the patient

Outcome Measures should reflect a standardized reporting time frame similar to that recommended by the SVS/ISCVS for endovascular procedures:

- Initial outcome = 30 days after procedure
- Short-term = 1 to 12 months, but statistically valid data* at least to 6 months
- Intermediate-term = 6 to 24 months, but statistically valid data* beyond 1 year
- Long-term = statistically valid data* beyond 2 years

* Life Table or Kaplan-Meier projections with standard error not exceeding 10% at this point.

Critical Issue 1: Relationship between different outcome measures
Methodological work is required to understand the relationship between traditionally used measures of medical effectiveness (eg, ABPI, patency), walking ability of the patient (eg, walking distance or walking impairment questionnaire), descriptive health status measures (eg, SF-36), and measures valuing quality of life (eg, HUI, EuroQol), especially in severe ischemia.

A 3.2.4 Objective Outcome Measures

As an objective measure of improvement, hemodynamic criteria are commonly used. An increase in the ABPI of more than 0.15 (as stand-alone criteria; 0.10 if combined with symptomatic criteria) or an increase in ABPI to more than 0.90 has been recommended as an objective measure of success.[5] If the ABPI cannot be measured accurately, for instance, in diabetic patients, the toe pressure may be substituted. The term *hemodynamic failure* indicates a lack of significant hemodynamic improvement as determined by an increase in ABPI, using distal pressures, regardless of whether the artery is patent. In evaluating exercise and drug regimens for claudication, however, the mean ABPI generally does not improve in spite of improvements in exercise performance and functional status.[13] To enable comparison between the results of revascularization and exercise or medical treatments, every clinical trial for IC should evaluate the severity and impact of claudication using a treadmill exercise test (see Recommendation 43, p S132).

A 3.2.5 Symptomatic Outcome Measures

Symptom severity and outcome of an intervention can be judged by classifying patients' symptoms on a scale. The two most well-known classifications are the Fontaine stages and Rutherford's categories, which is currently recommended to determine significant clinical improvement (Table 9).[5] Category 0 indicates the asymptomatic state; category 1, mild; 2, moderate claudication; and 3, severe claudication; 4, ischemic rest pain; 5, minor tissue loss; and

Table 9. Classification of peripheral arterial disease: Fontaine's stages and Rutherford's categories

Fontaine		*Rutherford*		
Stage	*Clinical*	*Grade*	*Category*	*Clinical*
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate-severe claudication	I	2	Moderate claudication
		I	3	Severe claudication
III	Ischemic rest pain	II	4	Ischemic rest pain
		III	5	Minor tissue loss
IV	Ulceration or gangrene	III	6	Major tissue loss

6, major tissue loss. Objective criteria are also part of the overall published clinical classification scheme and are based on the subject's ability to complete a treadmill exercise test. However, the objective criteria of improvement should probably be considered separately to avoid confusing "symptomatic improvement" and "objective improvement." Symptomatic improvement requires an upward shift of at least one category on the scale except for those with actual tissue loss (category 5) who must at least improve to a level of claudication to be considered improved.

A 3.2.6 Disease-Specific Health Status Questionnaires

Probably the oldest disease-specific questionnaire for intermittent claudication is the one developed by Rose.[22,23] Although not very sensitive, this questionnaire has been widely used in identifying patients with claudication.[24,25] The WIQ is a disease-specific instrument developed to characterize walking ability through a questionnaire as an alternative to treadmill testing. This has been demonstrated to be useful in intermittent claudication.[26] It includes questions about the degree of pain, aching, or cramps, the reason for the difficulty walking, walking distance, walking speed, and stair climbing. It is proposed that a disease-specific health status questionnaire be used to document symptomatic status. Currently, there is no disease-specific questionnaire for severe ischemia.

To assess the patient's activity level, the peripheral arterial disease Physical Activity Recall (PAD-PAR) questionnaire may be used; this is a measure of habitual physical activity and provides a global estimate of the total energy expended.[27] A combined generic- and disease-specific questionnaire was developed by McDaniel et al,[24] using items from several previously developed and tested instruments, including the instrumental activities of daily living questionnaire. The Spitzer QL-index, which was originally designed for application in oncology, has also been used for measuring quality of life in patients with PAD. [28,29]

Recommendation 2: Symptomatic outcome measures
To measure baseline and changes in symptomatic disease-specific health status, a disease-specific health status questionnaire should be used, such as the Walking Impairment Questionnaire (WIQ).

Critical Issue 2: Symptomatic outcome measures in acute and critical limb ischemia
There is a need for a validated disease-specific questionnaire for patients with acute or critical limb ischemia.

A 3.2.7 Generic Health Status Questionnaires

Several generic instruments are useful in gathering information regarding quality of life. Though somewhat different in format, each of these instruments attempts to obtain important data in four major categories: functional status assessment, perceived health, psychological well-being, and role function. *Functional status assessment* is directed toward determining how well the patient can perform basic physical tasks, such as the ability to climb stairs, read a newspaper, or

hold a pen. *Perceived health* identifies how healthy a patient believes he or she is and how much a patient worries about his or her health. *Psychological well-being* focuses on the extent to which patients become distressed, anxious, or depressed about their illnesses and associated treatments. *Role function* evaluation is directed toward the assessment of the impact of a patient's disorder on his or her ability to work and perform his or her obligatory duties, such as care for his or her family, and on his or her resources.

Studies evaluating health-related quality of life have demonstrated that patients with PAD have poorer scores on various measures of functional health and well-being compared with patients of similar age and sex without the disease.[20,21] The Medical Outcomes Study Short-Form 36 (SF-36) is a generic health status questionnaire that appears to be useful in evaluating quality of life in patients with PAD.[19,21,30] The SF-36 assesses eight health dimensions—physical functioning, social functioning, role limitations due to physical problems, role limitations due to emotional problems, pain, mental health, energy, general health perception—and a one-item question: change in health during the past year.

For each SF-36 dimension, item scores are coded, summed, and transformed onto a scale from 0 to 100, with 100 being the highest score. The RAND-36 (RAND Corporation) and the SF-36 are practically the same and have identical items, but the scoring is slightly different for the dimensions pain and general health perception.[31] The dimensions physical functioning and role limitations due to physical functioning and pain are especially affected by the presence of PAD (Figure 19). At least 8 of the 36 questions can be considered directly relevant for the evaluation of PAD, including questions about walking distance, the ability to climb stairs, and pain. The SF-36 (and RAND-36) is a generic measure that has been used in multiple settings and validated across a wide spectrum of diseases; therefore comparison with the outcomes of patients with

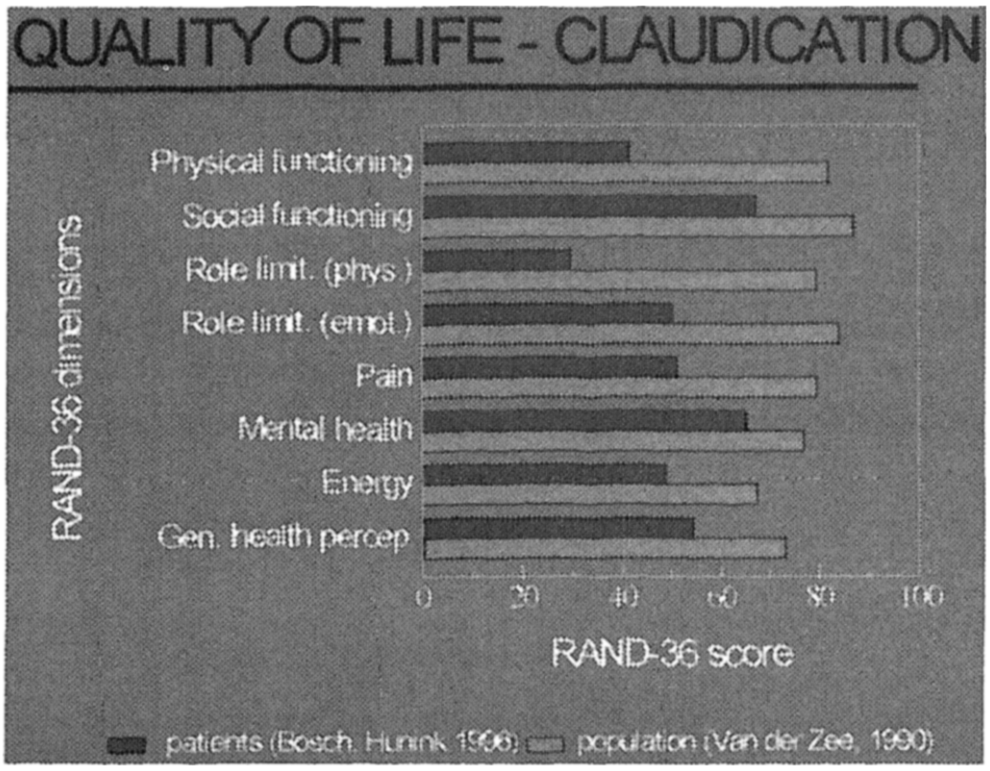

Figure 19: Quality of life assessed with the RAND 36-Item Health Survey 1.0 (mean scores with confidence intervals) in patients with peripheral arterial disease compared with the general population. Reproduced from Med Decis Making 1996;16:217-225.

other diseases and comparison with the healthy population are possible (Figure 19). Both the RAND-36 and SF-36 have been translated into several languages, and both can be completed by the patients themselves.

The Functional Status Questionnaire and instrumental activities of daily living have also been applied in the assessment of PAD.[24, 32] The Sickness Impact Profile (SIP) has been used in the assessment of PAD and in the United States in a randomized controlled clinical trial comparing the outcome of PTA and bypass surgery for PAD.[18,33,34,35] The Nottingham Health Profile (NHP) has been used in the United Kingdom in a study comparing PTA with medical treatment.[36,37,38] Both the SIP and NHP are fairly lengthy questionnaires. In measuring health-related quality of life, a number of issues, including validity, reliability, and feasibility, need to be considered. Such criteria have been proposed by various scientific groups (Association for Pharmacoeconomics and Outcomes Research [APOR], 1996; European Organisation for Research and Treatment of Cancer [EORTC]) and are increasingly requested by guidelines (Canadian Coordinating Office for Health Technology Assessment [CCOHTA], 1996; Gold et al, 1996).

The following criteria should be applied when choosing a measure of health-related quality of life, in particular for multinational clinical trials:

- Validity (the extent to which a technique measures what it is supposed to measure)
- Reliability (stability of scores)
- Feasibility (burden for the respondent and investigator)
- Responsiveness (likelihood of detecting a clinically important change or treatment effect)
- Cultural and language adaptations (standardized translations, linguistic evaluations, psychomotor validations, attention to cultural issues)

Recommendation 3: Generic health status outcome measures
Until better instruments are developed, if general health status is to be measured, the Short Form 36 (SF-36 or RAND-36) questionnaire is recommended to measure baseline and changes in generic health status.

A 3.2.8 Valuing Health-Related Quality of Life and Utility Assessment

To determine whether the additional costs incurred by performing an intervention are justified compared with the effectiveness gained, the gain in effectiveness needs to be valued.[1] The recommended approach is to express effectiveness in quality-adjusted life years (QALYs), which is a composite value combining both length and quality of life.[1] In estimating QALYs, every year spent in full health is counted as a full year. Years spent in less than full health are counted as some fraction of a year, as determined by the value of the health state. For example, if a subject enjoys 2 years of full health followed by 6 years in a health state with pain valued at 50% of the values of full health, the patients would have had 5 QALYs (ie, 2 + 50% of 6). Thus, calculating QALYs requires quantifying the quality of life in the various health states. A few studies have determined values for various health states related to PAD. Such holistic values reflect the relative value of life with the disease compared with perfect health. They may be expressed, for example, on a scale from zero to 1, where zero is equivalent to death and 1 equals perfect health comparable to contemporaries. These measures include the time trade-off, standard gamble, rating scale, visual analog scale, EuroQol, HUI, and Quality of Well-Being scale.[39,40,41,42,43,44]

In the *time trade-off*, patients are asked to choose between trading life expectancy to avoid morbidity versus living longer with morbidity. In the *standard gamble*, patients are asked to choose between taking a risk of immediate death to avoid the morbidity of less desirable health states versus the certainty of living with morbidity. Both the time trade-off and standard gamble determine the patient's point of indifference between trading life expectancy or taking risk, respec-

tively, and living with morbidity. The *rating scale* and *visual analog* methods require subjects to directly value health states on a scale from zero to 100, zero generally being equivalent to death and 100 perfect health, by either responding with a number or placing a mark on a line.

The *Health Utility Index, Quality of Well-Being Scale,* and *EuroQol* are all multi-attribute utility instruments that classify patients into one of many health states determined by their responses to questions on several dimensions (or attributes) of health. For each health state, a value can be calculated using a known formula that reflects how important each dimension is considered. This formula was derived using multi-attribute utility theory and determined by obtaining values from the general population based on generic scenarios describing the health state.[43] Typically, these multi-attribute values for claudication range from 0.60 to 0.85, from 0.30 to 0.45 for rest pain, and from 0.20 to 0.60 for amputation.[21,45] The obtained values depend on the questionnaire used. The standard reference gamble generally yields the highest values, followed by the time trade-off, rating or visual analog scale, and then the HUI. These differences are due to attitudes toward risk, how scales are interpreted, and whether the values are obtained from patients or the general public.

In general, the recommended perspective for performing a cost-effectiveness analysis is societal,[1] implying that values for such analyses should be obtained from the general public. Both the HUI and the EuroQol provide known societal values for generic health states, implying that one only needs to determine the patients' generic health states. In general, the HUI is recommended for obtaining values from the societal perspective. The EuroQoL can provide similar values with fewer questions and is easier to administer but discriminates less well between health states, is less sensitive to changes, and is not based on standard reference gamble utilities.[46] Alternatively, disease-specific scenarios of health states can be formulated based on the patients' experiences and a general population asked to value these scenarios, which for amputation especially yielded lower values than when the scenario was based on generic scenarios.[47]

Recommendation 4: Value/utility assessment
Valuing health-related quality of life is only necessary in the setting of a clinical trial with a cost-effectiveness study. The Health Utilities Index or EuroQol are recommended to obtain a single global value from the societal perspective based on the health status of the patient group under consideration. In daily clinical practice, one verbal rating scale question, or a visual analog scale question, can be used to obtain a global value for quality of life from the patient's perspective.

A 3.2.9 Patency

Determining patency is required for presentation of the results of percutaneous and surgical interventions in scientific journals. Patency should always be based on objective findings and should be distinguished from symptomatic and objective improvement as already defined. Whereas symptomatic and objective improvement both apply to the entire limb, patency applies to the revascularized or bypassed segment only. For patency, any one of five criteria must be met, of which the following two are the most relevant[5]:

- Demonstrably patent by vascular imaging using angiography, (color-guided) Duplex ultra sound or magnetic resonance angiography
- Maintenance of achieved improvement in the appropriate segmental limb pressure index; that is, not more than 0.10 below the highest postoperative index. If a drop of more than 0.10 is measured, imaging proof of patency is required. The most appropriate pressure index is the one at the next level beyond the revascularized segment or distal anastomosis.

A graft or revascularized segment is considered to have "primary" patency if it has had uninterrupted patency with *either* no procedure performed on it *or* a procedure (eg, transluminal dilation or a proximal or distal extension to a graft) to deal with disease progression *in the adjacent*

native vessel. Thus, the only exceptions that do *not* disqualify the graft for primary patency are procedures performed for disease *beyond* the graft or the revascularized segment. Dilation or minor revisions performed for stenoses, dilation, or other structural defects, or closing missed arteriovenous (AV) fistulas in an in situ vein bypass, *before* occlusion, *do not* constitute exceptions, because they are intended to prevent eventual failure of the revascularization procedure.

The additional designation of "assisted primary patency" applies to the special situation in which patency was never lost but rather maintained by prophylactic intervention. If patency of the revascularized segment is restored *after* occlusion, by thrombectomy, thrombolysis, or transluminal angioplasty, or if any problems with the revascularized segment itself, for example, the graft or one of its anastomoses, require revision or reconstruction, all *must* be listed under "secondary" patency. In the case of a graft, a "redo" or secondary reconstruction does *not* contribute to secondary patency, *unless most of the original graft and at least one anastomosis are retained in continuity.* Although the above definitions were originally developed for bypass grafts, they now can be equally applied to any type of revascularized segment, such as endarterectomy, PTA, or stenting, but it is generally agreed that the entire anatomic arterial segment should be considered as one, much like a bypass graft.

Recommendation 5: Definition of patency
Vascular imaging is the reference standard for determining patency. In its absence, patency may be defined as maintenance of achieved hemodynamic improvement in the relevant segment; ie, not more than 0.10 below the highest postoperative index. If a drop of more than 0.10 is measured, proof of patency with vascular imaging is required.

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